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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,829	09/09/2003	Nikolai M. Krivitski	86017.000037	1750
23387	7590	10/03/2007	EXAMINER	
Stephen B. Salai, Esq. Harter, Secrest & Emery LLP 1600 Bausch & Lomb Place Rochester, NY 14604-2711			PANI, JOHN	
			ART UNIT	PAPER NUMBER
			3736	
			MAIL DATE	DELIVERY MODE
			10/03/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/657,829

Applicant(s)

KRIVITSKI ET AL.

Examiner

John Pani

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 12/10/03, 3/09/07.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 5-14 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 3,726,269 to Webster ("Webster").

3. Webster teaches

In reference to Claim 5

A catheter (**10**) comprising: (a) an elongate catheter body (**12**) having a distal end and a proximal end, the elongate catheter body including an indicator lumen (fluid flow passage **16**); and (b) a guide wire (**26**) extending through a length of the indicator lumen (See Fig. 7).

In reference to Claim 6

The catheter of claim 5 (see above), wherein the indicator lumen terminates at the distal end of the elongate catheter body (see col. 5 lines 1-3).

In reference to Claim 7

The catheter of claim 5 (see above), wherein the indicator lumen has a reduced cross sectional area ("reduced inner diameter", col. 5 lines 1-10) adjacent the distal end of the elongate catheter body.

In reference to Claim 8

The catheter of claim 5 (see above), wherein the indicator lumen has a reduced cross sectional area adjacent the distal end of the elongate catheter body ("reduced inner diameter", col. 5 lines 1-10) and the guidewire is sized to be slideably received through the reduced cross sectional area ("permit guidewire **26** to be passed through the catheter").

In reference to Claim 9

The catheter of claim 5, wherein the indicator lumen has a reduced cross sectional area adjacent the distal end of the elongate catheter body ("reduced inner diameter", col. 5 lines 1-10) and the guidewire is sized to reduce passage of an indicator through the reduced cross sectional area of the indicator lumen (By fitting through the anterior passage of the catheter, the guidewire inherently is sized to reduce passage of an indicator, as this reduces the cross sectional area across which the indicator can flow, and thereby reduces the passage/flow).

In reference to Claim 10

The catheter of claim 5 (see above), wherein the indicator lumen terminates adjacent the distal end of the elongate catheter body (inherently, as the lumen allows the guidewire to pass out of it, see Fig. 7).

In reference to Claim 11

The catheter of claim 5 (see above), wherein the indicator lumen includes a terminal port at the distal end of the elongate catheter body (the distal opening that

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allows passage of guidewire) and a radial injection port (apertures **27**) spaced from the terminal port (see Fig. 7).

In reference to Claims 12 and 13

The catheter of claim 5 (see above), further comprising a dilution sensor connected to the elongate catheter body, wherein the dilution sensor is a thermistor (dilution thermistor **42**, col. 7 lines 14-18, it is connected through **19**, which is connected to **23**, which is connected to **12**, see Figs. 4 and 7).

In reference to Claim 14

A method of introducing an indicator through a catheter, the method comprising:  
(a) passing a guidewire (**26**) through an indicator lumen (**16**) in an elongate catheter body (**12**, see Fig. 7); and (b) passing the indicator ("coolant medium") through the indicator lumen to pass from the elongate catheter body (see col. 4 lines 1-10).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster in view of US Pat. No. 5,782,811 to Samson et al. ("Samson").

In reference to Claims 15, 16, 17, and 18

Webster teaches the method of claim 14 (see above), and further teaches that the anterior end of the catheter is restricted so as to force coolant to flow preferentially out of the side apertures rather than from the anterior end (see col. 5 lines 1-45). However, Webster does not expressly disclose simultaneously passing or locating the guidewire and indicator through the indicator lumen, passing the guidewire through a reduced cross sectional area of the indicator lumen to reduce passage of the indicator through the lumen or to increase flow of the indicator through a radial injection port.

Samson (see Fig. 13) teaches of a catheter (**530**) which uses a guidewire assembly (**532**) as a means for controlling the fluid flow of diagnostic materials into a selected site (see col. 14 lines 1-11). A number of openings (**538**) are located radially in the catheter, and the guidewire is used to selectively alter flow through a desired opening.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the method of Webster by passing a guidewire assembly through the reduced diameter anterior end in order to reduce passage of the coolant, as taught by Samson, and motivated by Webster. This would provide the benefit that the flow could be selectively controlled, as taught by Samson. It would have been further obvious to use the guidewire to increase the flow through the radial ports of Webster, as taught by Samson, as this would also increase the user's ability to control flow rates through the side apertures, and Webster discloses the desirability of forcing flow through the radial apertures. This would require the guidewire and indicator both being

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simultaneously passed through the indicator lumen (as Samson teaches moving the guidewire valve portion **34** to vary flow) and located in the indicator lumen.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Pani whose telephone number is 571-270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JP 9/28/07



MAX HINDENBURG

SENIOR PATENT EXAMINER

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